

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY
(Chapter II of the Patent Cooperation Treaty)
(PCT Article 36 and Rule 70)

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| Applicant's or agent's file reference 047956/288189 | FOR FURTHER ACTION See Form PCT/IPEA/416 | |
| International application No. PCT/US04/25682 | International filing date (day/month/year) 09 August 2004 (09.08.2004) | Priority date (day/month/year) 07 August 2003 (07.08.2003) |
| International Patent Classification (IPC) or national classification and IPC IPC(7): A61M 29/00 and US Cl.: 606/108, 623/1.12 | | |
| Applicant ALVELUS, INC. | | |

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets, including this cover sheet.

3. This report is also accompanied by ANNEXES, comprising:

a. ☒ (sent to the applicant and to the International Bureau) a total of 1 sheets, as follows:

☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).

☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.

b. ☐ (sent to the International Bureau only) a total of (indicate type and number of electronic carrier(s)) _____, containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒ Box No. I Basis of the report

☐ Box No. II Priority

☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

☐ Box No. IV Lack of unity of invention

☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

☐ Box No. VI Certain documents cited

☐ Box No. VII Certain defects in the international application

☐ Box No. VIII Certain observations on the international application

| | |
|--|---|
| Date of submission of the demand 27 September 2005 (27.09.2005) | Date of completion of this report 01 February 2006 (01.02.2006) |
| Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201 | Authorized officer For <i>Virginia Libby</i> Michael Thaler Telephone No. (703) 308-0858 |

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/US04/25682

Box No. I Basis of the report

1. With regard to the language, this report is based on:

- ☒ the international application in the language in which it was filed.
- ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
- ☐ publication of the international application (under Rule 12.4(a))
- ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☐ the international application as originally filed/furnished
- ☒ the description:
pages 1-16 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☒ the claims:
pages 19-30 as originally filed/furnished
pages* NONE as amended (together with any statement) under Article 19
pages* 18 received by this Authority on 27 September 2005 (27.09.2005)
pages* NONE received by this Authority on _____
- ☒ the drawings:
pages 1-8 as originally filed/furnished
pages* NONE received by this Authority on _____
pages* NONE received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages _____
- ☐ the claims, Nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to the sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/25682**Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. Statement**

| | | |
|-------------------------------|----------------------------|-----|
| Novelty (N) | Claims <u>1-86</u> | YES |
| | Claims <u>NONE</u> | NO |
| Inventive Step (IS) | Claims <u>33-60, 84-86</u> | YES |
| | Claims <u>1-32, 61-83</u> | NO |
| Industrial Applicability (IA) | Claims <u>1-86</u> | YES |
| | Claims <u>NONE</u> | NO |

2. Citations and Explanations (Rule 70.7)

Claims 1-32 and 61-83 lack an inventive step under PCT Article 33(3) as being obvious over Mathis (6,599,314). Mathis discloses tube 100, wherein the passageway within the tube 100 is obviously a cavity. As to claims 1 and 61, for example, it would have been obvious to use a self-sealing membrane with tube 100 since such membranes are old and well known as coatings for stents. Note that such a stent coating would be "disposed over the first end" of the Mathis tube 100 as recited in claim 1, line 4 since the first end of the tube 100 is considered to be the entire end portion of the tube including the wall of the tube.

Claims 33-60 and 84-86 meet the criteria set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest the combination of an outer tubular member with grooves and tracks having tabs slidably coupled therein

Claims 1-86 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

----- NEW CITATIONS -----

CLAIMS:

What is claimed is:

1 1. A therapeutic medical appliance for introduction into a cavity in the
2 anatomy of a patient, the medical appliance comprising a tube with first and
3 second ends and the tube defining a cavity extending between the first and second
4 ends; and a first self-sealing membrane disposed over the first end.

1 2. The therapeutic medical appliance of claim 1, wherein tube forms a
2 scaffolding such that when pressure is exerted along varying points of the
3 extension of the appliance, the appliance does not undesirably foreshorten or
4 elongate.

1 3. The therapeutic medical appliance of claim 2, wherein along the
2 extension of the appliance, the scaffolding forms geometrical patterns.

1 4. The therapeutic medical appliance of claim 2, wherein the
2 scaffolding further comprises a coating coupled with the scaffolding, the coating of
3 sufficient thickness to prevent the medical appliance from becoming epithelialized
4 when installed in the desired portion of the patient's anatomy.

1 5. The therapeutic medical appliance of claim 4, wherein the coating
2 does not inhibit flexing or radial expansion of the medical appliance.

1 6. The therapeutic medical appliance of claim 5, wherein the coating is
2 coupled with the medical appliance about the first and second ends thereof.

~~REPLACEMENT PAGE~~

AMENDED SHEET